K130931

510 (k) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS FOR

EASY DAY (methafilcon A)1-Day Soft (hydrophilic) Contact Lens for Daily Wear

Prepared Date: Aug. 20, 2013

AUG 3 0 2013

Submitter Information:

Company:	Jiangsu Horien Contact Lens Co., Ltd.
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Contact Person:	Jinhua Hu
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Identification of Device:

Classification Name:	Lens, Contact, (Disposable)
Trade Name:	EASY DAY (methafilcon A)1-Day Soft (hydrophilic) Contact Lens
Common or usual Name:	Soft (hydrophilic) Contact lens (daily wear)
FDA Classification:	Class II

Predicate Device:

FREQUENCY 55, FREQUENCY 55 ASPHERIC, ENCORE, ENCORE TORIC, ONEVUE, COOPERFLEX (methafilcon A) Soft (hydrophilic) Contact Lens cleared via K000384 COOPERVISION, INC.

Indications for Use

EASY DAY (methafilcon A) 1-Day Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia) in not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 0.75 diopters that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from 0 ~ -12.00D. The lens is indicated for single use daily disposable wear and patients are instructed to discard the lens after each removal.

Description of Device

EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) contact lens is available as a single vision aspherical lens. The lens material, methafilcon A is a copolymer of 2-hydroxyethyl

methacrylate (HEMA) and methacrylic acid (MAA) cross-linked with ethylene glycol dimethacrylate (EGDMA) .The lens with visible tint is tinted blue using reactive blue 4K to make the lens more visible for handling. Lenses are supplied sterile in sealed blister packers containing buffered saline solution.

Summary of Clinical Study:

The EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lenses for Daily Wear were tested at least 30 evaluable subjects' eyes separately for 1 month. Nearly a hundred percent of the participants' vision was corrected and nearly all were satisfied with the lens wearing and care of lenses. In general, these products are good and safe for customers.

Nonclinical Studies:

A series of nonclinical performance tests were performed to demonstrate the safety and effectiveness of the EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lens for Daily Wear, and establish substantial equivalence to predicate lenses - FREQUENCY 55, FREQUENCY 55 ASPHERIC, ENCORE, ENCORE TORIC, ONEVUE, COOPERFLEX (methafilcon A) Soft (hydrophilic) Contact Lens (K000384). All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses,* and in conformance to applicable device regulations. The evidence of substantial equivalent to the predicate lens described as follow:

a) Technological characteristics studies

EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lens for Daily Wear designs in the following parameter ranges:

Diameter range:14.20 ±0.2mm

Power range: -0.0 D to -12.00 D

Center Thickness: 0.06~0.100mm varies with power

Lenses have the following properties:

Refractive index: 1.409 ±0.005

Light transmittance: >92%

Water content: 53 to 57 %

Oxygen permeability (edged corrected): 19.7±20% { 10^{-11}[$(cm^2/sec)(ml O_2/ml\text{-}mmHg)$] }

There characterizations of EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lenses are equivalent and comparable to those of predicate lenses.

b) Biocompatibility

"In accordance with the May 1994 FDA guideline titled Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses, toxicity studies have been conducted on the model: EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lens

for Daily Wear. The Irritation test in the rabbit eye and Systemic toxicity studies indicate the extracts would be considered as non-toxic and nor irritated. The Cytotoxicity testing demonstrates the lens is not cytotoxic under the conditions of the study.

c) Microbiology

Steam sterilization process has been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA Group 4. There is shelf-life stability data supporting that the lens remains sterile through the expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and addictive residues.

Substantial equivalence Statement:

Testing performed on the EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lens for Daily Wear indicated that it can support the efficiency and security use as well as the predicate devices- FREQUENCY 55, FREQUENCY 55 ASPHERIC, ENCORE, ENCORE TORIC, ONEVUE, COOPERFLEX (methafilcon A) Soft (hydrophilic) Contact Lens (K000384), when used in accordance with the instructions for use. It is due to the facts that the risks and benefits of the subject device are the same as soft contact lenses for to the daily wear.

In conclusion, it is Jiangsu Horien's EASY DAY (methafilcon A)1-Day Soft (hydrophilic) Contact Lens conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the EASY DAY (methafilcon A) 1-Day Soft (hydrophilic) Contact Lens for Daily Wear, with the same established safety profile and effectiveness as the predicate device-- FREQUENCY 55, FREQUENCY 55 ASPHERIC, ENCORE, ENCORE TORIC, ONEVUE, COOPERFLEX (methafilcon A) Soft (hydrophilic) Contact Lens (K000384).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 30, 2013

Jiangsu Horien Contact Lens Co., Ltd.
% Ms. Jennifer Reich
Harvest Consulting Corp
2904 N. Boldt Drive,
Flagstaff, AZ 86001

Re: K130931
Trade/Device Name: EASY DAY(methafilcon A) 1-Day Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact lens (daily wear)
Regulatory Class: Class II
Product Code: LPL
Dated: July 29, 2013
Received: July 19, 2013

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130931

Device Name: EASY DAY (methafilcon A) 1-Day Soft (Hydrophilic) Contact Lens

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The lens is indicated for single use daily disposable wear and patients are instructed to discard the lens after each removal.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Livshitz
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2013.08.23
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K130931____